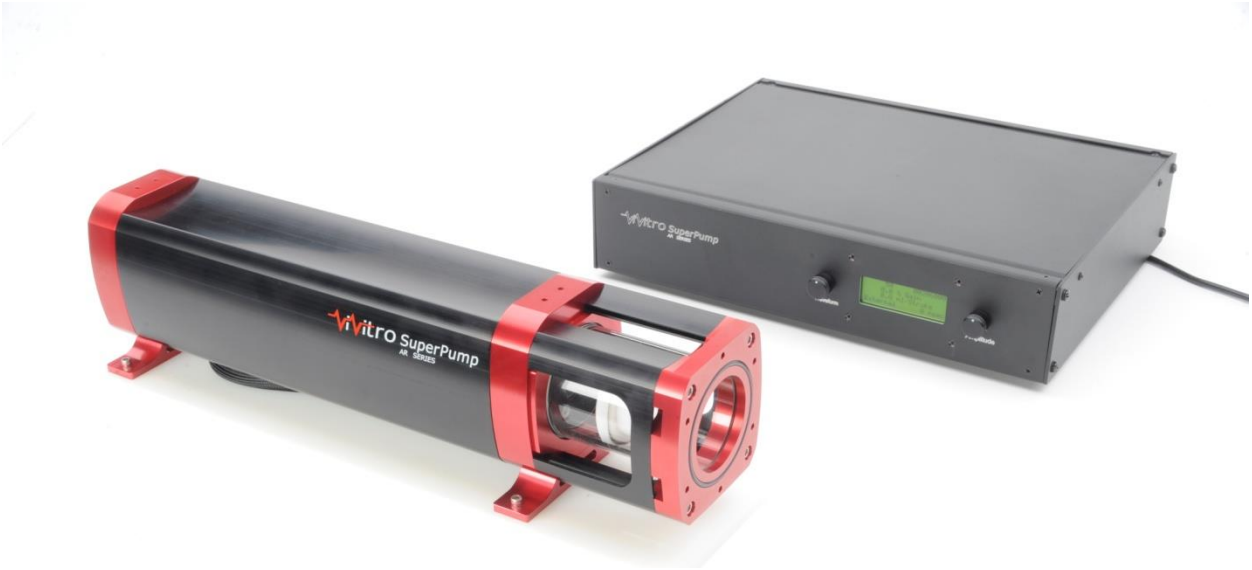
SuperPump System User Manual

AR Series



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ViVitro Labs SuperPump-AR series System

Designed and Distributed by *ViVitro Labs Inc*., BC, Canada

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About ViVitro Labs

ViVitro Labs offers industry leading prosthetic heart valve test equipment and related testing and consulting services. Since our formation in 1984, we have worked closely with our clients – universities, medical device manufacturers and regulatory agencies – to support their research, regulatory and production requirements.

Our vision is to empower our clients to complete world-leading research, develop high quality, innovative products and ensure that they demonstrate regulatory compliance.

What we offer

ViVitro Labs' respected clients come from all over the world and include leaders in the cardiovascular implant industry.

Academic Research

ViVitro Labs is a leading vendor to academic labs worldwide. Hundreds of citations refer to the use of ViVitro Labs' equipment. For example, the ViVitro Labs SuperPump has become a worldwide standard for the generation of physiological pressure waveforms in academic research applications.

Laboratory and Production Services

Almost every significant prosthetic valve company in the world has ViVitro Labs equipment in their research laboratories. ViVitro Labs services include:

- *Verification of Hydrodynamic Testing – ISO 5840:2005 Annex L*
- *Durability Testing – ISO 5840:2005 Annex M*
- *And other design specific testing.*

Other Product Services

ViVitro Labs also provides a variety of product services which are found in many manufacturers' production and QC systems. ViVitro Labs product services include:

- *Customized testing systems*
- *Custom production function testers*
- *QC test and inspection equipment*

Contents

1 Cautions and Warnings 5

2 About the AR series *SuperPump* 6

2.1 System Hardware 6

2.2 Features 6

3 Initial Set-Up Procedures 7

3.1 Unpacking – list of components 7

3.2 Installing the *SuperPump* 7

3.3 Front Panel 8

3.4 Rear Panel 8

3.5 Electrical Requirements 9

3.6 Fuses 9

4 Running the System 10

4.1 Waveform Source 10

4.2 Initialize System 11

4.3 Select Waveform 12

4.4 Set Sync Delay 12

4.5 Change the Cycle Count 13

4.6 Pump Operation 13

4.7 Cleaning 15

5 Faults and Alarms 14

5.1 Emergency Stop 14

5.2 Limit Switch 14

5.3 Pump Error 14

6 Specifications 15

7 Pump Mounting Details 20

7.1 Mounting feet bolt pattern 20

7.2 Pump cylinder mounting face bolt pattern 20

8 ViviGen Software 21

8.1 Installation 21

8.2 Method 21

8.3 Icons 21

8.4 Status Request 22

8.5 New waveform creation 22

8.6 Software License Agreement 23

1 Cautions and Warnings

Read all of the instructions before operating the *SuperPump*

This instrument is intended for research use only and must be operated by trained lab personnel.

To ensure adequate cooling of the *SuperPump* controller and pump, place on a clean, flat surface, and be sure that there is at least 10 cm (4 in) of clearance around each side of the controller and motor end of the pump. Make sure that the fan vent is not blocked.

Always connect the power supply to a 3-prong, grounded AC outlet rated 4A, 110–240 V using the AC power cord provided with the *SuperPump*. Do not use an adapter to an ungrounded outlet. Before plugging the instrument in, be sure that the correct fuses are installed. See section 3.6

Electrical devices pose the risk of electric shock. To reduce the risk of shock, do not open any covers that are fastened with screws.

While *SuperPump* is designed to withstand spills on its exterior surface, do not allow fluids to enter the interior of the instrument. In the event of such a spill, disconnect the power cable before cleaning up.

Do not operate *SuperPump* in extreme humidity or in conditions that can create condensation. Protect the instrument against dust and moisture, and avoid physical shock and strong forces.

Clean the controller and pump exterior with a dry cloth. Disconnect power before cleaning

Use caution when moving the controller and/or pump. Disconnect power and pump cable before moving the system to a new location.

Do not use the *SuperPump* system if there is evidence of physical damage or if the system has been dropped or subject to impact.

Do not attempt to service the product beyond what has been described in this manual. All other servicing should be referred to qualified service personnel.

2 About the AR series *SuperPump*

2.1 System Hardware

The *Advanced Research series SuperPump System* made by *ViVitro Labs Inc*. consists of a digital amplifier with stroke volume display and preprogrammed waveforms driving a piston-in-cylinder pump.

The pump piston is located by a ball screw/servo motor/encoder unit driven by a motor controller which compares actual position against the desired position defined by the input waveform. The precision of the ball screw and the resolution of the encoder ensure accurate positioning of the piston resulting in the desired pulsatile flow.

The controller can be used stand alone by selecting one of the built in waveforms or an external signal can be input. *ViVigen* software is included with the pump to allow the generation of custom waveforms which can then be uploaded to the controller via the built in USB port. The *SuperPump* is designed for use as part of the *ViVitro Pulse Duplicator* and includes the required inputs and outputs for this. These same I/O including analog outputs for position, dl/dt (flow) and the sync pulse make the *SuperPump* adaptable to any custom test apparatus.

The *ViVitro Labs AR series SuperPump* is ideal for testing a variety of cardiovascular devices.

2.2 Features

The *SuperPump-AR series* from *ViVitro Labs Inc.* features include:

- Digital precision control of a pump-in-cylinder designed linear actuator used to generate physiological flows;
- Stand-alone capability with five (5) preprogrammed cardiac waveforms created by user;
- Range of capable rates are 4 to 200 beats per minute;
- Range of stroke volume 0 to 150 ml;
- Digital controlled and created waveforms by ViViGen or ViViTest software;
- Control, create, input or store cardiac waveforms at various physiological states and frequencies through ViVitro software or other std waveform generating equipment;
- Manufactured by an ISO 13485 accredited facility designed to meet regulatory requirements (ISO 5840 and FDA) or research needs.

NOTE: The user may opt to manipulate the system to achieve alternate states/results/configurations. Should the user carry this out it should be noted that the pressures and flows are kept within the limitations of the system to ensure the system is not overloaded.

3 Initial Set-Up Procedures

The *SuperPump System* has several steps to the main mechanical sub-assemblies, and a few steps for the electrical components installation/configuration.

NOTE: It is critical for the assembly steps to be followed in order to assure successful operation.

3.1 Unpacking – list of components

The *SuperPump AR* arrives in 2 containers; a wooden shipping crate for the pump and a cardboard container for the controller. Inspect the shipping containers for external damage. Retain the shipping carton and packing materials for possible re-shipment. Inspect the system components for damage. If there is evidence of damage contact the carrier, initiate a damage claim, and inform *ViVitro Labs*.

The *SuperPump* arrives pre-assembled with the following parts:

- Mounting base
- Linear Actuator with Cable
- Standard Pump Head
- Actuator Extension Cable
- *SuperPump* Controller
- USB flash drive with ViVigen software

3.2 Installing the *SuperPump*

The *SuperPump* is supplied mounted to a rigid plastic base for use on a bench top. Optionally the pump may be mounted directly to a structure or test apparatus using #10-32 fasteners through the mounting feet of the pump. See bolt pattern layout at the end of the document.

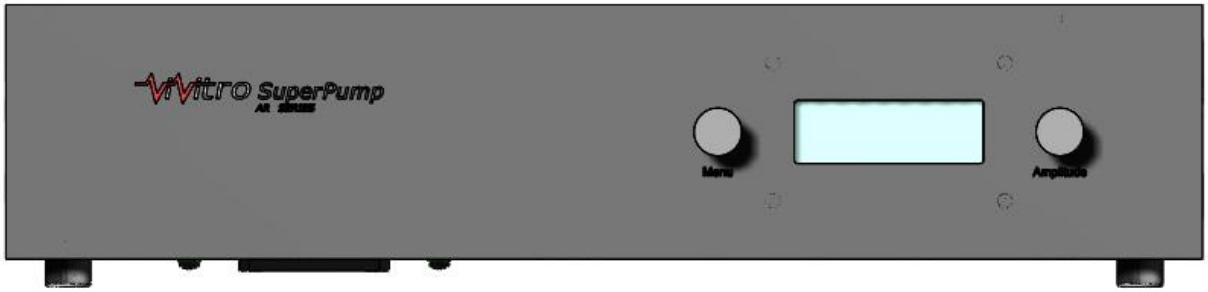
It is recommended that the *SuperPump* be mounted horizontally. The back side of the pump cylinder is provided with a drain; however vertical mounting of the pump can result in water entering the ball screw/motor causing an electrical hazard.

The controller should be located away from the pump to avoid any water or test fluid. An extension cable is provided to allow extra separation if required.

It is recommended that the pump act on the test fluid through a membrane to maintain isolation between working and test fluid. The piston should not be directly exposed to blood analog solution or saline. Distilled water is recommended as the working fluid.

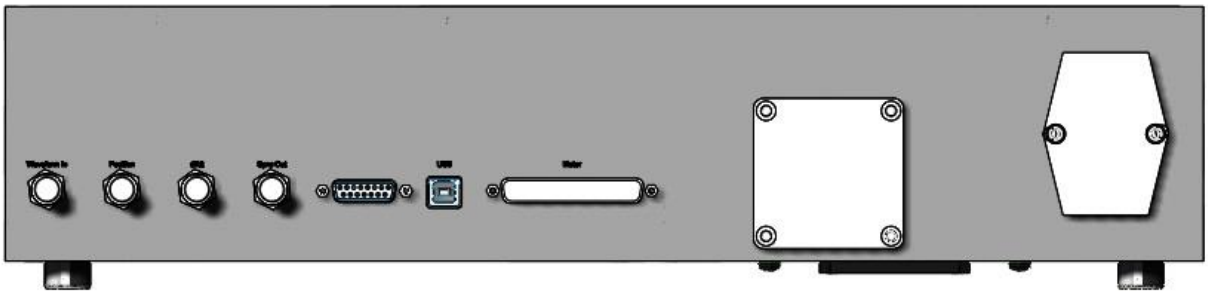
When connecting the controller to other equipment such as computers or a signal generator ensure all equipment is on the same ground. Ground loops can cause noise or signal offsets which will result in a noisy or inconsistent waveform. Any test setup should be validated by running known samples before testing.

3.3 Front Panel



The front panel consists of 2 controls and the display. The controls are rotary encoders with push switches. To the left of the display is the menu knob which allows scrolling by turning the knob and selection by pressing the knob. To the right of the display is the amplitude knob which adjusts the amplitude of the output waveform and starts and stops the pump by pressing the knob

3.4 Rear Panel



The rear panel contains all of the connectors. From left to right:

- **Waveform In**: BNC connector used when an external signal is used as the waveform
- **Position**: BNC connector analog output signal for the piston position
- **dl/dt**: BNC connector analog output signal proportional to instantaneous flow rate
- **Sync Out**: BNC connector 5V TTL signal triggered at the rising zero crossing of the waveform. The timing of the signal can be adjusted to any point in the waveform
- Troubleshooting port : no user accessible functions
- **USB**: For uploading custom waveforms created using *ViVigen* software or for use with *ViVitest* when the *SuperPump* is used as part of the *Pulse Duplicator*
- **Motor**: Cable connection to the pump
- Cooling fan
- Power input: Power cord, fuse holder and main power on/off

3.5 Electrical Requirements

ViVitro Labs Inc. will endeavor to have your system's components adapted to meet your country's power supply, however, as an extra precaution, it is advised that all equipment designated to be connected to a power supply be checked prior to use.

Use only the power cord supplied with your *SuperPump*. The controller must be plugged into a grounded outlet rated for 300W.

3.6 Fuses

Two fuses are supplied and required for the *SuperPump Controller*. They are located in the fuse drawer on the power input module on the back of the controller.

At 120VAC use two 4A, 5mm x 20mm 230V fuses.

At 230VAC use two 2A, 5mm x 20mm 230V fuses.

Contact *ViVitro Labs* if you require replacement fuses.

4 Running the System

4.1 Waveform Source

The *SuperPump* may be operated using either:

a) USB connection to a computer running *ViViTest Software* – see *ViViTest* user manual

b) Internally stored waveform – see section 8 *ViVigen*

c) Externally generated waveform

If an external waveform is to be used, plug an appropriate BNC cable from the waveform source to the Waveform In port on the back of the *SuperPump Controller* (sec 2.4).

The external waveform should conform to the following specifications:

- Amplitude: ±5.0 V maximum. Any waveform that exceeds this amplitude will not be accurately represented in the pump movement.
- Rate [Frequency]: 4 bpm (beats per minute) minimum to 200 bpm maximum. [0.067 Hz to 3.33 Hz]

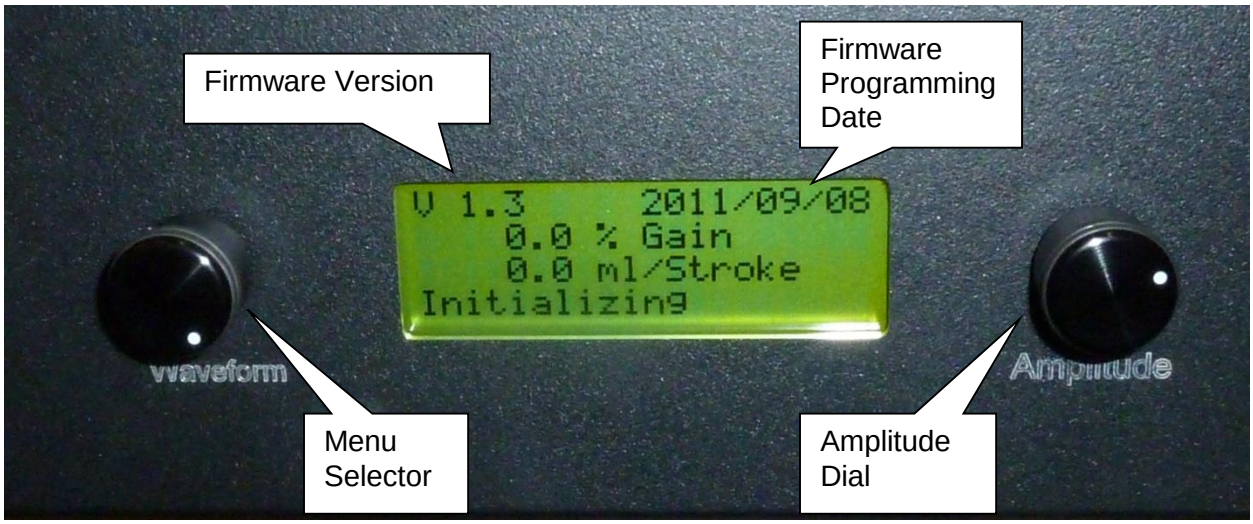
NOTE: Do not input waveforms with frequency greater than the listed maximum.

- Form: Bi-polar. The waveform should be centered about 0 V (ground), without D.C. offset, unless offset is intended for recreating a particular wave shape. The peak-to-peak limits with offset must still remain within ±5.0 V relative to ground.
- Noise and Distortion: both noise and distortion will affect the accuracy of the pump movement; therefore the signal source should be clean, with THD+N (total harmonic distortion and noise) below 5%.

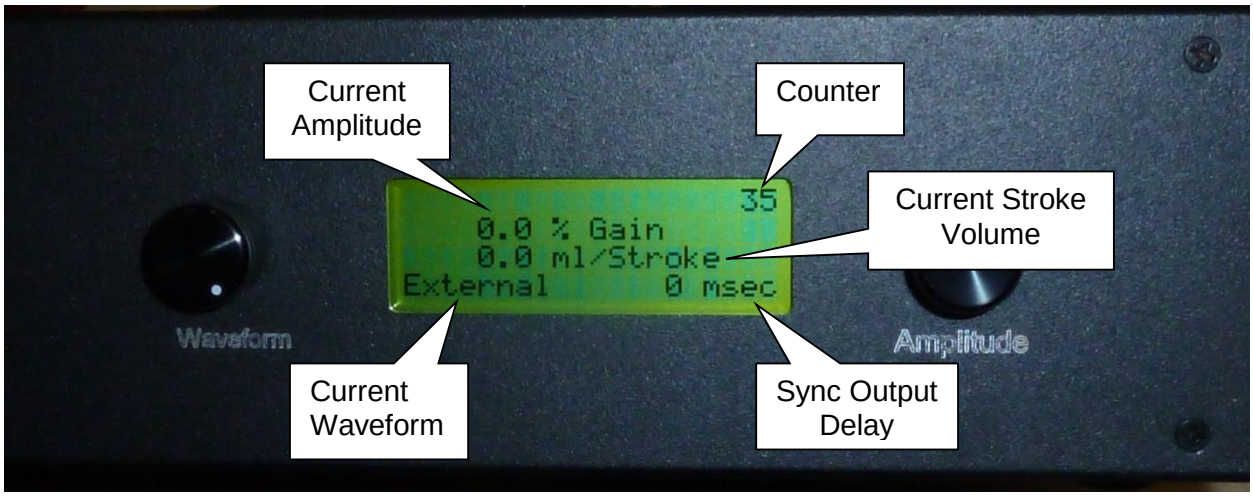
Note: the maximum velocity of the piston is limited to approximately 60mm/sec. As amplitude and frequency are increased the velocity will also increase. If the pump cannot match the desired waveform a pump error will result. In this case either the maximum slope of the waveform must be reduced or the frequency or amplitude must be reduced.

4.2 Initialize System

Turn on the power switch on the back of the Controller. The screen on the front of the Controller will light up and indicate that it is Initializing. It will then automatically begin a Homing Pump sequence.

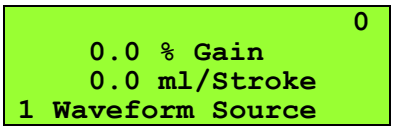


After automatically Homing Pump, the screen should appear as below. The most recently used waveform source will appear in the Current Waveform section.

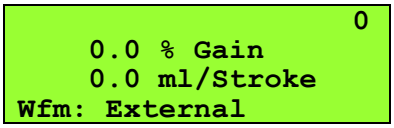


4.3 Select Waveform

Press the Menu Selector Dial. Turn the Menu dial until “1 Waveform Source” appears as below.

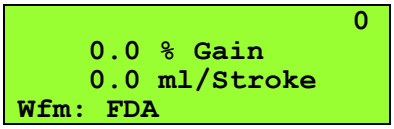


While the message Waveform Source is on the screen, press the dial again. The screen will now indicate the most recently used waveform source.



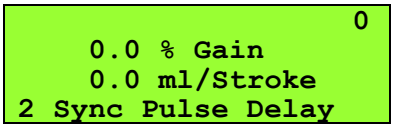
If the current waveform source is desired press the dial again to escape the waveform selector. If a stored waveform is desired turn the dial clockwise and press the dial when you have chosen the correct waveform.

Refer to Section 8 *ViVigen* to load standard waveforms edit or create waveforms and load them onto the *SuperPump Controller*.



4.4 Set Sync Delay

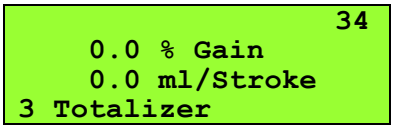
Press the Menu Selector Dial. Turn the menu knob until “2 Sync Pulse Delay” is on the screen, press the dial again. The screen will now indicate the current sync delay in msec.



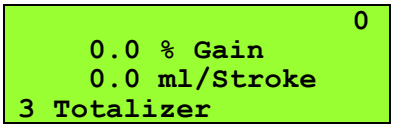
To adjust the delay turn the dial until the correct delay is displayed and then press the dial.

4.5 Change the Cycle Count

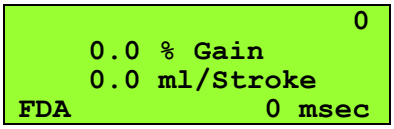
Press the Menu Selector Dial. Turn the menu knob until “3 Totalizer” is on the screen, press the dial again.



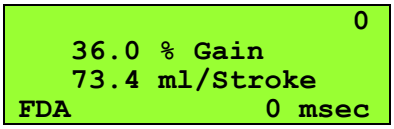
To adjust the counter turn the dial until the correct value is displayed and then press the dial.



4.6 Pump Operation



Turn the Amplitude Dial until the desired stroke volume is reached. For example:

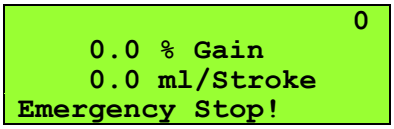


To stop the pump either turn the Amplitude Dial to 0 or press the Amplitude Dial. In this case an Emergency Stop alarm will appear. To clear this alarm, press the Amplitude Dial. The pump will automatically perform a Homing Sequence.

5 Faults and Alarms

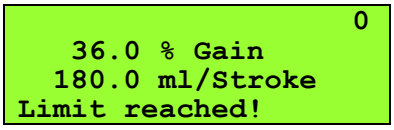
5.1 Emergency Stop

If case of an Emergency Stop, press the Amplitude Dial to clear the alarm and Home the pump.



5.2 Limit Switch

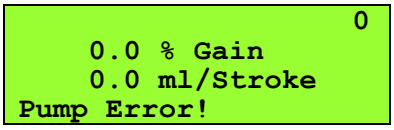
The *SuperPump* actuator contains a factory-set limit sensor for the maximum push and pull stroke. In case of a Limit reached alarm, press the Amplitude Dial to clear the alarm and Home the pump.



5.3 Pump Error

If the Controller loses communication with the Pump or if the Pump is unable to move, a Pump error message will appear. If this occurs,

1. turn off the system
2. check that the cables are properly installed
3. ensure that the pump is free of mechanical interference and damage
4. turn the controller on and allow it to initialize normally
5. If the alarm persists, contact the manufacturer



6 Maintenance and Cleaning

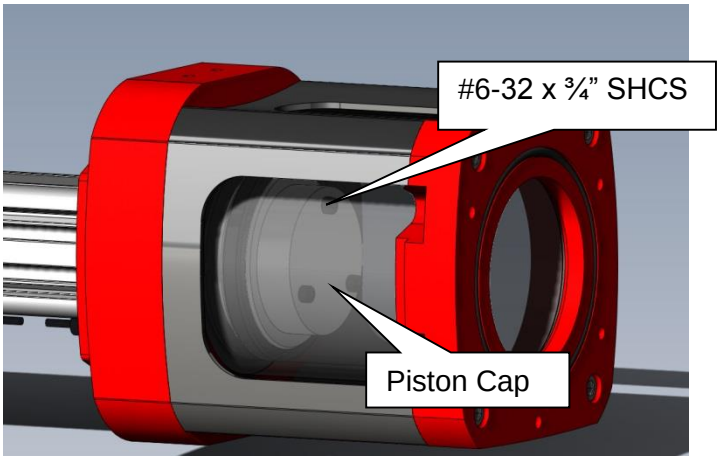
6.1 Cleaning

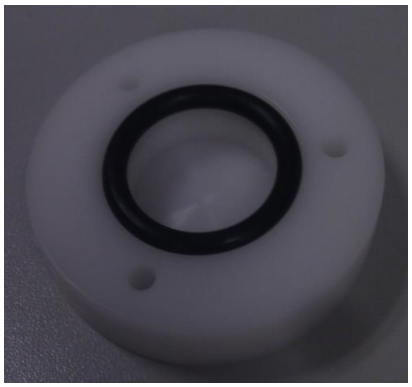
The controller outer surface should be cleaned with a dry cloth only.

The outer surface should be cleaned with a dry cloth only. The pump cylinder may be flushed with distilled water or, in the case of contamination, mild detergent and water followed by rinsing with distilled water.

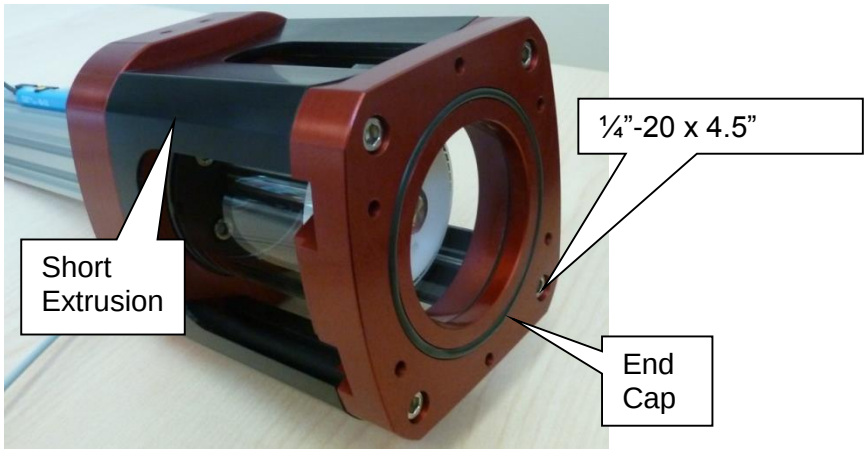
6.2 Piston Seal Replacement

1. Remove the three #6-32 x ¾" screws located on the front of the piston and remove the *SuperPump* Piston Cap (09533).

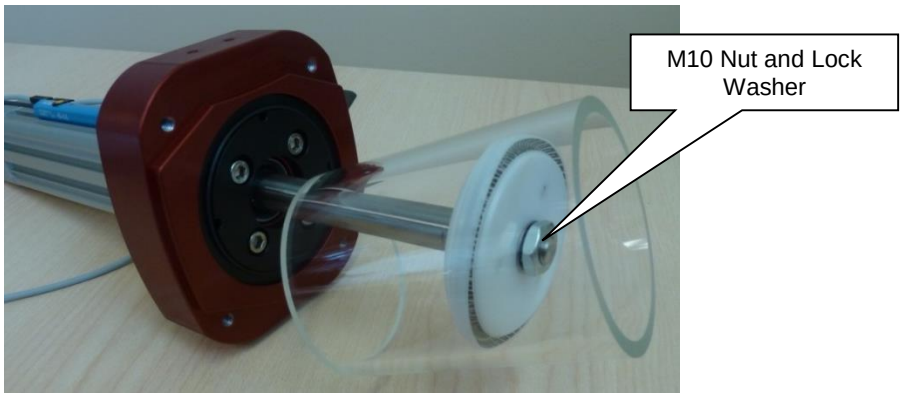




2. Remove the four ¼"-20 x 4.5" screws on the front of the pump head.



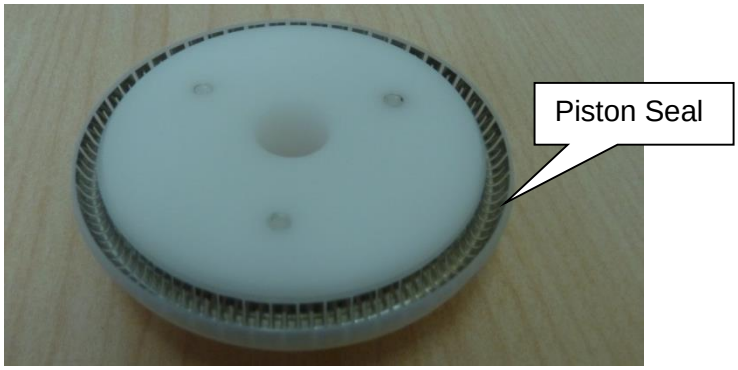
3. Remove the Short Extrusion (08981) and end cap from the pump assembly.



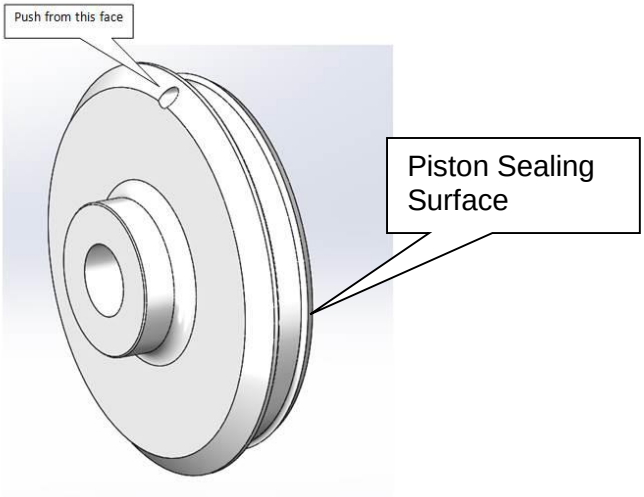
4. Carefully remove the glass cylinder from the piston.

CAUTION: DURING THIS STEP BE CAREFUL WHEN HANDLING THE GLASS CYLINDER AS THE EDGES MAY BE SHARP.

5. Remove the M10 nut and lockwasher from the front of the piston.
6. Remove the *SuperPump* Piston (09532) from the rod end.



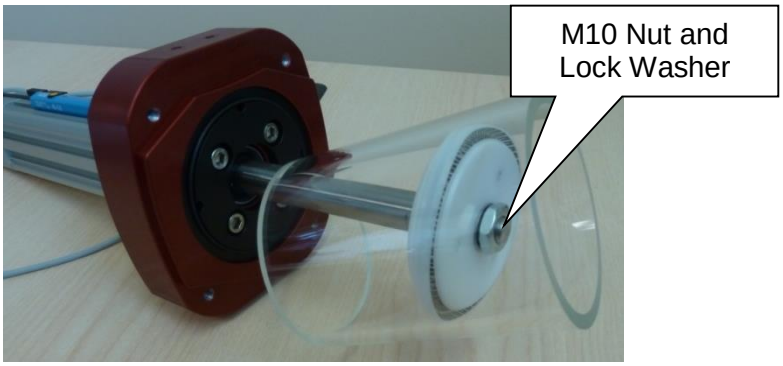
7. Locate the small hole near the outer edge of the piston. Holding the piston firmly, press off the piston seal with a small hex key. Be sure not to scratch or damage the piston sealing surface during this step.



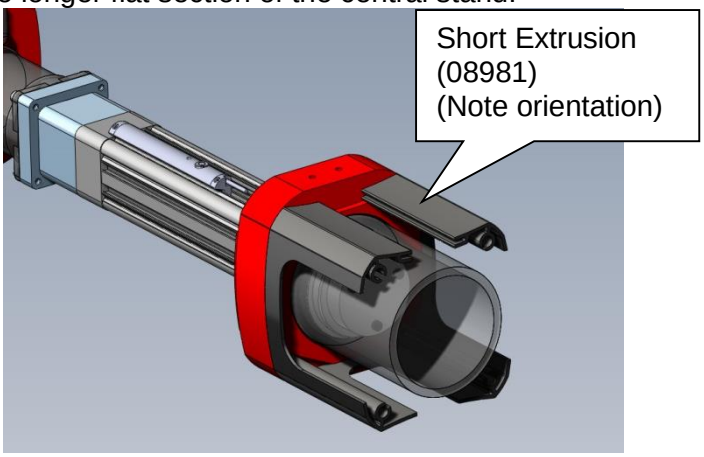
8. Check the sealing surface of the piston for scratches that are either visible or can be felt with a fingernail. Ensuring the orientation is correct, snap the piston seal onto the piston carefully by hand.

9. Clean any dust and debris from the glass cylinder. Apply two pieces of electrical tape to one edge of the glass cylinder.

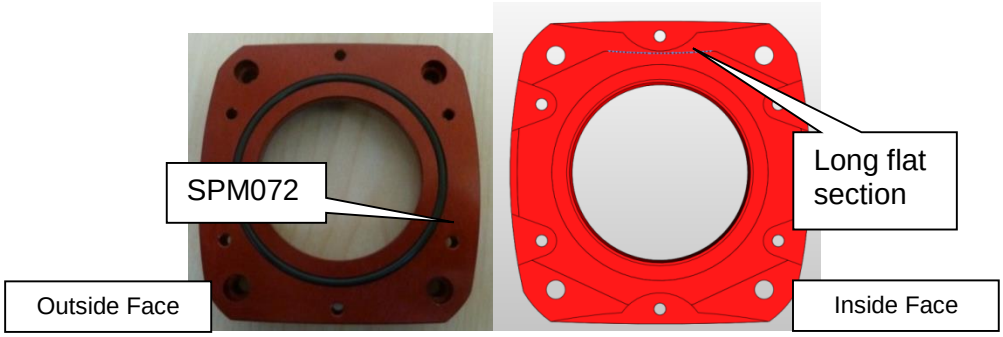
10. Push the piston into the glass cylinder (SPM042) using the tape as a glide point. Remove the electrical tape from the Glass Cylinder (SPM042).
11. Slide rod end into the *SuperPump* Piston (09532). Fasten in place with a M10 Lock Washer (09538), Loctite, and the nut from the rod end. Ensure the glass cylinder does not bump against the cylinder rod.



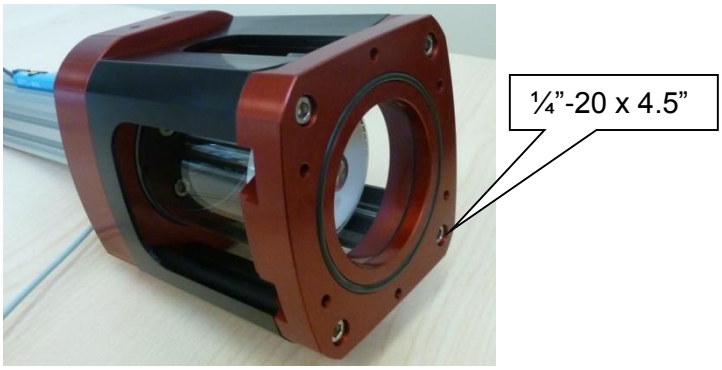
12. Push the Glass Cylinder (SPM042) onto the pump. Ensure that the piston does not come close to the sharp edge of the glass cylinder.
13. Place the Short Extrusion (08981) onto the pump. The gap in the short extrusion should be in line with the longer flat section of the central stand.



14. Push O-Ring-235 (SPM072) into the groove on the outside face of End Cap (08975).
15. Push O-Ring-335 (10084) into the groove on the inside face of End Cap (08975).



16. **F**asten the End Cap (08975) onto the pump head with four ¼”-20 x 4.5” SHCS (08980). Take care not to chip the edge of the glass with the aluminum parts. Tighten the fasteners gradually to prevent uneven stress on the glass cylinder. Compress the sides of the Short Extrusion (08981) while tightening so that the sides sit flush with the end cap faces.



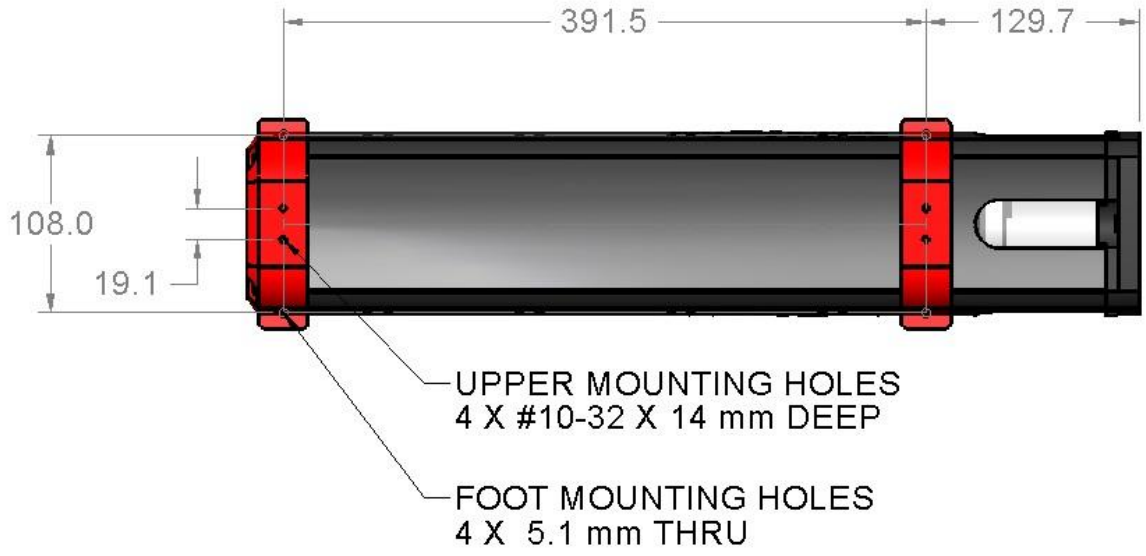
17. Check for damage on O-Ring (09534) into the recess of the SuperPump Piston Cap (09533).
18. Fasten the *SuperPump* Piston Cap (09533) to the *SuperPump* Piston with three #6-32 x ¾” SHCS (HCM079). Loctite is not required.

7 Specifications

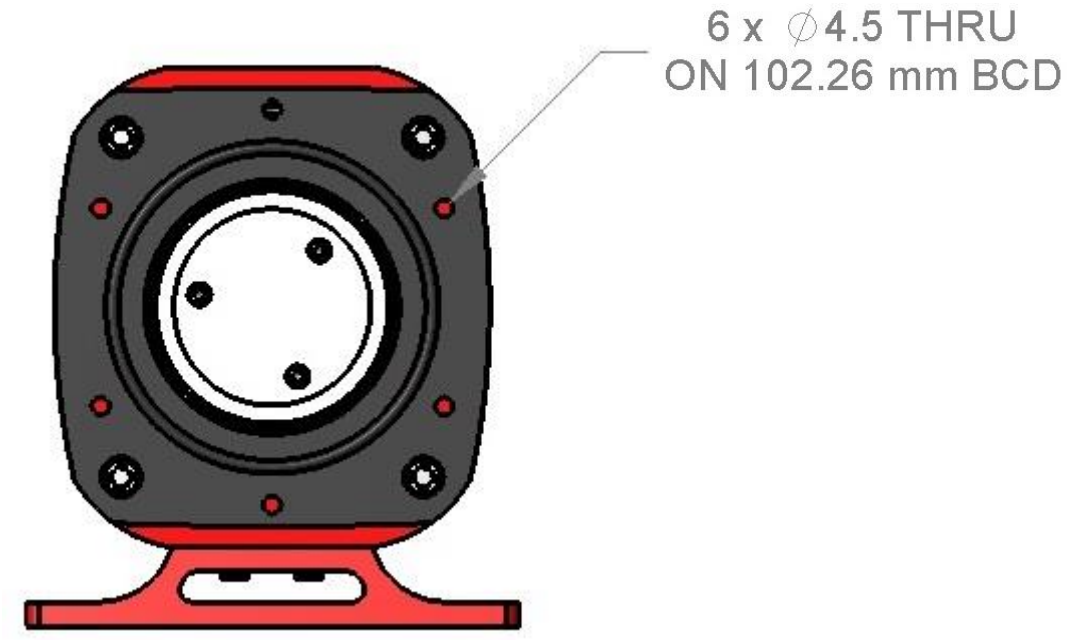
Pump	
Pump bore diameter	Nominal 69.85mm (2.750”)
Pump stroke	0-50mm (±25mm)
Displacement	0-180mL/stroke
Rate	4 to 200 beats per minute
Maximum pressure	200 mmHg
Inputs	
External Waveform	± 5 V 0.067 Hz to 3.33 Hz (4 to 200 beats per minute)
Outputs	
Position	-5 to 5 V (200mV/mm)
dl/dt	-5 to 5 V (539 ml/s/V)
Sync	+5V TTL LE at rising zero crossing
Electrical Requirements	
Voltage	90-240 VAC / 50-60Hz
Power	Max 300W
Dimensions	
Controller	11 x 48 x 33 cm
Pump	15 x 55 x 17 cm
Environmental	
Operating Temperature	10 to 35ºC
Operating Humidity	15 to 75%
Operating pressure (elevation)	700-1060 hPa
Shipping/Storage Temperature	-20 to 50 ºC
Shipping/Storage Humidity	15 to 95%
No restriction on pressure during shipping/storage	

8 Pump Mounting Details

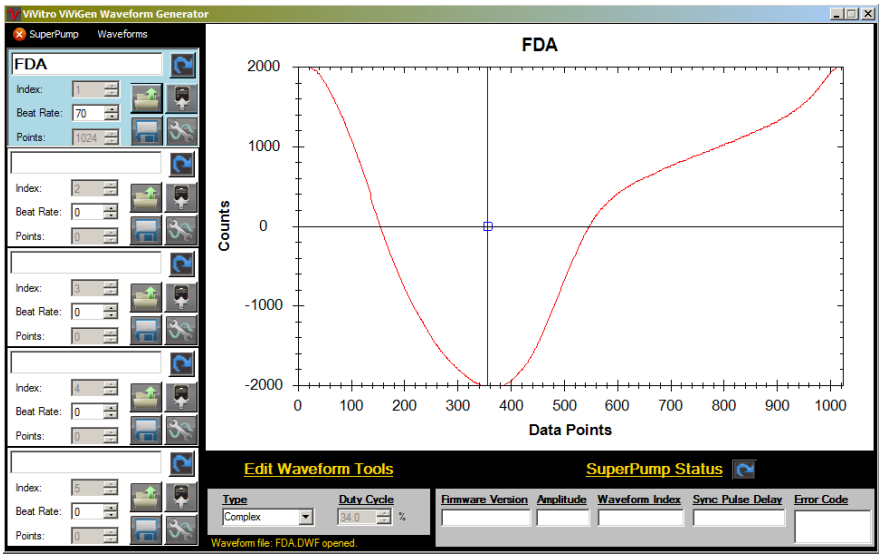
8.1 Mounting feet bolt pattern



8.2 Pump cylinder mounting face bolt pattern



9 ViviGen Software



9.1 Installation

Install the ViVigen Installer.exe on the computer. This executable program can be found on the supplied flash drive.

During installation setup, check the box “Create a desktop icon.”

9.2 Method

Connect the SuperPump Amplifier to the computer using the USB cable.

Turn on the amplifier.

Open the ViViGen shortcut icon on the desktop.

Click the SuperPump label on the upper left corner to access the drop-down menu.

Select “Connect...” and select a “COMX” value.

If the connection is successful, the red dot will turn green.

Click the SuperPump label on the upper left corner to access the drop-down menu.

Select “Refresh Waveforms” to upload current waveforms from the amplifier to the Waveform Generator console.

The amplifier and the console are able to access five waveforms.

9.3 Icons

The left side of the console panel shows five index positions. These correspond to the five waveforms stored in the amplifier. It is possible to modify these waveforms using the four icons and the drop-down boxes for each position.

Use the “Open File” icon to search for a stored waveform in the software package. Open the file and view the waveform on the graph.

Use the “Tools” icon to modify or edit the waveform, its label or its Beat Rate. Be sure to define the Type and Duty Cycle, under the “Edit Waveform Tools.” Note: The “Beat Rate” has a max value of 400. Do not use a beat rate higher than 200 when running the SuperPump.

Use the “Save” icon to save the modified waveform to a file.

Use the “Refresh” icon to view your changes. Note: Remember to save your waveform, before using the “Refresh” icon, when making changes under “Edit Waveform Tools.”

Use the “Send” icon to send the waveform to the amplifier.

Note: Do not attempt to “Refresh” or “Upload” a waveform when the SuperPump is running.

9.4 Status Request

Use the “Refresh” icon beside the “SuperPump Status” label to update the screen view with the current status of the pump. Note: the amplitude number represents a percentage value, not a stroke volume.

Waveform index gives the index number of the waveform currently being used by the amplifier.

Sync pulse delay is given in milliseconds, and can be adjusted using the amplifier controls.

Observe the error code box, under the “SuperPump Status.” Any communications failures or other problems will be signalled here. Note that an attempt to communicate with the amplifier will be repeated until successful or the software is terminated.

Note: If the USB is disconnected and then reconnected, the “Refresh Status” will not update. The SuperPump must be reconnected using drop-down menu, in upper left corner.

9.5 New waveform creation

New waveforms may be created using the drop-down menu from the Waveforms label in the upper left corner.

Select “New” and complete the requested data in the “Create New Waveforms” window. Note that 1024 is the standard and expected number of Points.

Enter its Label name, its Beat Rate, and its Waveform Type.

Select the “Save” icon and name the file appropriately. Select “Done” when completed.

The new waveform may now be accessed from one of the five index positions, and the duty cycle and beat rate adjusted as required.

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